

protection that it provides pursuant to paragraph 1 or 2 in the event that the patent protection terminates on a date earlier than the end of the term of such protection.

4. With respect to any pharmaceutical product that is subject to a patent:
 - (a) each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process;
 - (b) the Party shall provide that the patent owner shall be notified of the identity of any third party requesting marketing approval effective during the term of the patent; and
 - (c) the Party shall not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or with the acquiescence of the patent owner.

ARTICLE 16.9 : ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

General Obligations

1. Each Party shall ensure that in judicial and administrative proceedings for the enforcement of intellectual property rights, decisions on the merits of a case, that under the law or practice of the Party are of general application, shall preferably be in writing and shall state the reasons on which the decisions are based.
2. Each Party shall ensure that its laws and regulations, procedures, final judicial decisions, and administrative rulings of general application pertaining to the enforcement of intellectual property rights shall be published, or where such publication is not practicable, made publicly available, in a national language, in such a manner as to enable the other Party and right holders to become acquainted with them. Nothing in this paragraph shall require a Party to disclose confidential information the disclosure of which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private.
3. Each Party shall inform the public of its efforts to provide effective enforcement of intellectual property rights in its civil, administrative, and criminal system, including any statistical information that the Party may collect for such purposes.
4. The Parties understand that a decision that a Party makes on the distribution of enforcement resources shall not excuse that Party from complying with this Chapter.

5. Each Party shall provide for civil remedies against the actions described in paragraphs 7 and 8 of Article 16.4. These shall include at least:

- (a) provisional measures, including seizure of devices and products suspected of being involved in the prohibited activity;
- (b) the opportunity for the right holder to elect between actual damages it suffered (plus any profits attributable to the prohibited activity not taken into account in computing the actual damages) or pre-established damages;
- (c) payment to a prevailing right holder of court costs and fees and reasonable attorney's fees by the party engaged in the prohibited conduct at the conclusion of the civil judicial proceeding; and
- (d) destruction of devices and products found to be involved in the prohibited conduct.

6. In civil, administrative, and criminal proceedings involving copyright or related rights, each Party shall provide for a presumption that, in the absence of proof to the contrary, the natural person or legal entity whose name is indicated as the author, producer, performer, or publisher of the work, performance, or phonogram in the usual manner, is the designated right holder in such work, performance, or phonogram. Each Party shall also provide for a presumption that, in the absence of proof to the contrary, the copyright or related right subsists in such subject matter.

Civil and Administrative Procedures and Remedies for the Enforcement of Intellectual Property Rights

7. Each Party shall make available to right holders¹⁶⁻¹⁵ civil judicial procedures concerning the enforcement of any intellectual property right.

8. Each Party shall provide that in civil judicial proceedings, its judicial authorities shall have the authority, at least with respect to works, phonograms, and performances protected by copyright or related rights, and in cases of trademark infringement, to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer engaged in infringing activity, as well as the profits of the infringer that are attributable to the infringement and are not taken into account in computing the actual damages. In addition, in determining injury to the right holder, the judicial authorities shall, *inter alia*, consider the value of the

¹⁶⁻¹⁵ For the purpose of Article 16.9 concerning the enforcement of intellectual property rights, the term "right holder" shall include exclusive licensees as well as federations and associations having the legal standing to assert such rights; and the term "exclusive licensee" shall include the exclusive licensee of any one or more of the exclusive rights encompassed in a given intellectual property.

infringed-upon good or service, according to the suggested retail price of the legitimate good or service.

9. In civil judicial proceedings, each Party shall, at least with respect to works, phonograms and performances protected by copyright or related rights, and in cases of trademark counterfeiting, establish or maintain pre-established damages that shall be available on the election of the right holder. Each Party shall provide that pre-established damages shall be in an amount sufficiently high to constitute a deterrent to future infringements and with the intent to compensate the right holder for the harm caused by the infringement.

10. Each Party shall provide that its judicial authorities, except in exceptional circumstances, shall have the authority to order, at the conclusion of the civil judicial proceedings concerning copyright or related rights and trademark counterfeiting, that a prevailing right holder shall be paid court costs or fees and reasonable attorneys' fees by the infringing party.

11. In civil judicial proceedings concerning copyright or related rights infringement and trademark counterfeiting, each Party shall provide that its judicial authorities shall have the authority to order the seizure of suspected infringing goods and any related materials and implements used to accomplish the prohibited activity.

12. Each Party shall provide that:

- (a) in civil judicial proceedings, at the right holder's request, goods that have been found to be pirated or counterfeit shall be destroyed, except in exceptional cases;
- (b) its judicial authorities have the authority to order that materials and implements which have been used in the creation of the infringing goods be, without compensation of any sort, promptly destroyed or, in exceptional cases, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements; and
- (c) in regard to counterfeit trademarked goods, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of goods into the channels of commerce.

13. Each Party shall provide that in civil judicial proceedings, its judicial authorities shall have the authority to order the infringer to identify third parties that are involved in the production and distribution of the infringing goods or services and their channels of distribution and to provide this information to the right holder. Each Party shall provide that its judicial authorities shall have the authority to fine or imprison, in appropriate cases, persons who fail to abide by valid orders issued by such authorities.

Provisional Measures Concerning the Enforcement of Intellectual Property Rights

14. Each Party shall provide that requests for relief *inaudita altera parte* shall be dealt with expeditiously in accordance with the Party's judicial rules.

15. Each Party shall provide that:

- (a) its judicial authorities have the authority to require the plaintiff to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the plaintiff's right is being infringed or that such infringement is imminent, and to order the plaintiff to provide a reasonable security or equivalent assurance set at a level sufficient to protect the defendant and to prevent abuse, and so as not to unreasonably deter recourse to such procedures.
- (b) in the event that its judicial or other authorities appoint experts, technical or otherwise, that must be paid by the plaintiff, such costs should be closely related, *inter alia*, to the quantity of work to be performed and should not unreasonably deter recourse to such relief.

Special Requirements Related to Border Measures Concerning the Enforcement of Intellectual Property Rights

16. Each Party shall provide that any right holder initiating procedures for suspension by the Party's customs authorities of the release of suspected counterfeit trademark or pirated copyright goods¹⁶ into free circulation shall be required to provide adequate evidence to satisfy the competent authorities that, under the law of the importing country, there is *prima facie* an infringement of the right holder's intellectual property right and to supply sufficient information that may reasonably be expected to be within the right holder's knowledge to make the suspected goods reasonably recognizable to the customs authorities.

17. Each Party shall provide that its competent authorities shall have the authority to require an applicant to provide a reasonable security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Each Party shall provide that the security or assurance shall not unreasonably deter recourse to these procedures.

¹⁶ For the purposes of this Chapter:

(a) **counterfeit trademark goods** shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation; and

(b) **pirated copyright goods** shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

18. Where its competent authorities have made a determination that goods are counterfeit or pirated, the Party shall grant its competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer, and the consignee, and of the quantity of the goods in question.

19. Each Party shall provide that its competent authorities may initiate border measures *ex officio*, without the need for a formal complaint from a private party or right holder. Such measures shall apply to shipments of pirated and counterfeit goods imported into or exported out of a Party's territory, including shipments consigned to a local party. For transshipped goods that are not consigned to a local party, each Party shall, upon request, endeavor to examine such goods. For products transshipped through the territory of a Party destined for the territory of the other Party, the former shall cooperate to provide all available information to the latter Party to enable effective enforcement against shipments of counterfeit or pirated goods. Each Party shall ensure that it has the authority to undertake such cooperation in response to a request by the other Party on counterfeit or pirated goods en route to that other Party.

20. Each Party shall provide that goods that its competent authorities have determined to be pirated or counterfeit shall be destroyed, except in exceptional cases. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of the goods into the channels of commerce. In no event shall the competent authorities be authorized to permit the export of counterfeit or pirated goods.

Criminal Procedures and Remedies for the Enforcement of Intellectual Property Rights

21. Each Party shall provide criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale. Willful copyright or related rights piracy on a commercial scale includes (i) significant willful infringements of copyright or related rights that have no direct or indirect motivation of financial gain, as well as (ii) willful infringements for purposes of commercial advantage or financial gain.

(a) Specifically, each Party shall provide:

- (i) remedies that include imprisonment as well as monetary fines sufficiently high to deter future acts of infringement consistent with a policy of removing the monetary incentive of the infringer. Also, each Party shall encourage its judicial authorities to impose such fines at levels sufficient to provide a deterrent to future infringements;
- (ii) that its judicial authorities have the authority to order the seizure of suspected counterfeit or pirated goods, any related materials and implements that have been used in the commission of the offense, any assets traceable to the infringing activity, and documentary evidence relevant to the offense that fall within the scope of such order. Items that are subject to seizure pursuant to such order need not be individually

identified so long as they fall within general categories specified in the order;

- (iii) that its judicial authorities shall, except in exceptional cases, order the forfeiture and destruction of all counterfeit or pirated goods, and, at least with respect to willful copyright or related rights piracy, materials and implements that have been used in the creation of the infringing goods. Each Party shall further provide that such forfeiture and destruction shall occur without compensation of any kind to the defendant; and
- (iv) that its authorities may initiate legal action *ex officio*, without the need for a formal complaint by a private party or right holder.
- (b) Each Party may provide procedures for right holders to initiate private criminal actions. However, these procedures shall not be unduly burdensome or costly for right holders. Each Party shall ensure that non-private criminal actions are the primary means by which it ensures the effective enforcement of its criminal law against willful copyright or related rights piracy. In addition, each Party shall ensure that its competent authorities bring criminal actions, as necessary, to act as a deterrent to further infringements.

Limitations on Liability for Service Providers

22. Each Party shall provide, consistent with the framework set forth in Article 16.9:

- (a) legal incentives for service providers to cooperate with copyright¹⁶⁻¹⁷ owners in deterring the unauthorized storage and transmission of copyrighted materials; and
- (b) limitations in its law regarding the scope of remedies available against service providers for copyright infringements that they do not control, initiate, or direct, and that take place through systems or networks controlled or operated by them or on their behalf, as set forth in this subparagraph.¹⁶⁻¹⁸
 - (i) These limitations shall preclude monetary relief and provide reasonable restrictions on court-ordered relief to compel or restrain certain actions for the following functions and shall be confined to those functions:¹⁶⁻¹⁹

¹⁶⁻¹⁷ For purposes of Article 16.9.22, “copyright” shall also include related rights.

¹⁶⁻¹⁸ It is understood that this subparagraph is without prejudice to the availability of defenses to copyright infringement that are of general applicability.

¹⁶⁻¹⁹ Either Party may request consultations with the other Party to consider how to address future functions of a similar nature under this paragraph.

- (A) transmitting, routing or providing connections for material without modification of its content, or the intermediate and transient storage of such material in the course thereof;
 - (B) caching carried out through an automatic process;
 - (C) storage at the direction of a user of material residing on a system or network controlled or operated by or for the service provider; and
 - (D) referring or linking users to an online location by using information location tools, including hyperlinks and directories.
- (ii) These limitations shall apply only where the service provider does not initiate the chain of transmission of the material, and does not select the material or its recipients (except to the extent that a function described in clause (i)(D) in itself entails some form of selection).
- (iii) Qualification by a service provider for the limitations as to each function in clauses (i)(A) through (i)(D) shall be considered separately from qualification for the limitations as to each other function, in accordance with the conditions for qualification set forth in subparagraphs (iv) – (vii).
- (iv) With respect to functions referred to in clause (i)(B), the limitations shall be conditioned on the service provider:
- (A) permitting access to cached material in significant part only to users of its system or network who have met conditions on user access to that material;
 - (B) complying with rules concerning the refreshing, reloading, or other updating of the cached material when specified by the person making the material available online in accordance with a generally accepted industry standard data communications protocol for the system or network through which that person makes the material available;
 - (C) not interfering with technology consistent with industry standards accepted in the territory of each Party used at the originating site to obtain information about the use of the material, and not modifying its content in transmission to subsequent users; and
 - (D) expeditiously removing or disabling access, on receipt of an effective notification of claimed infringement, to cached material that has been removed or access to which has been disabled at the originating site.

- (v) With respect to functions referred to in clauses (i)(C) and (i)(D), the limitations shall be conditioned on the service provider:
 - (A) not receiving a financial benefit directly attributable to the infringing activity, in circumstances where it has the right and ability to control such activity;
 - (B) expeditiously removing or disabling access to the material residing on its system or network on obtaining actual knowledge of the infringement or becoming aware of facts or circumstances from which the infringement was apparent, such as through effective notifications of claimed infringement in accordance with subparagraph (ix) and
 - (C) publicly designating a representative to receive such notifications.
- (vi) Eligibility for the limitations in this subparagraph shall be conditioned on the service provider:
 - (A) adopting and reasonably implementing a policy that provides for termination in appropriate circumstances of the accounts of repeat infringers; and
 - (B) accommodating and not interfering with standard technical measures accepted in the territory of each Party that protect and identify copyrighted material, that are developed through an open, voluntary process by a broad consensus of copyright owners and service providers, that are available on reasonable and nondiscriminatory terms, and that do not impose substantial costs on service providers or substantial burdens on their systems or networks.
- (vii) Eligibility for the limitations in this subparagraph may not be conditioned on the service provider monitoring its service, or affirmatively seeking facts indicating infringing activity, except to the extent consistent with such technical measures.
- (viii) If the service provider qualifies for the limitations with respect to the functions referred to in clause (i)(A), court-ordered relief to compel or restrain certain actions shall be limited to terminating specified accounts, or to taking reasonable steps to block access to a specific, non-domestic online location. If the service provider qualifies for the limitations with respect to any other function in clause (i), court-ordered relief to compel or restrain certain actions shall be limited to removing or disabling access to the infringing material, terminating specified accounts, and other remedies that a court may find necessary provided that such other

remedies are the least burdensome to the service provider among comparably effective forms of relief. Each Party shall provide that any such relief shall be issued with due regard for the relative burden to the service provider and harm to the copyright owner, the technical feasibility and effectiveness of the remedy, and whether less burdensome, comparably effective enforcement methods are available. Except for orders ensuring the preservation of evidence, or other orders having no material adverse effect on the operation of the service provider's communications network, each Party shall provide that such relief shall be available only where the service provider has received notice of the court order proceedings referred to in this subparagraph and an opportunity to appear before the judicial authority.

- (ix) For purposes of the notice and take down process for the functions referred to in clauses (i)(C) and (D), each Party shall establish appropriate procedures for effective notifications of claimed infringement, and effective counter-notifications by those whose material is removed or disabled through mistake or misidentification. Each Party shall also provide for monetary remedies against any person who makes a knowing material misrepresentation in a notification or counter-notification that causes injury to any interested party as a result of a service provider relying on the misrepresentation.
- (x) If the service provider removes or disables access to material in good faith based on claimed or apparent infringement, each Party shall provide that the service provider shall be exempted from liability for any resulting claims, provided that, in the case of material residing on its system or network, it takes reasonable steps promptly to notify the person making the material available on its system or network that it has done so and, if such person makes an effective counter-notification and is subject to jurisdiction in an infringement suit, to restore the material online unless the person giving the original effective notification seeks judicial relief within a reasonable time.
- (xi) Each Party shall establish an administrative or judicial procedure enabling copyright owners who have given effective notification of claimed infringement to obtain expeditiously from a service provider information in its possession identifying the alleged infringer.
- (xii) For purposes of the functions referred to in clause (i)(A), **service provider** means a provider of transmission, routing or connections for digital online communications without modification of their content between or among points specified by the user of material of the user's choosing, and for purposes of the functions referred to in clauses (i)(B) through (i)(D)

service provider means a provider or operator of facilities for online services or network access.

ARTICLE 16.10 : TRANSITIONAL PROVISIONS

1. Each Party shall implement the obligations of this Chapter within the following periods:
 - (a) Each Party shall ratify or accede to the UPOV Convention and give effect to the obligations in paragraph 4 of Article 16.4 within six months of the date of entry into force of this Agreement or December 31, 2004, whichever date is earlier;
 - (b) each Party shall ratify or accede to the agreements listed in paragraph 2(a) of Article 16.1(except for the UPOV Convention) and give effect to Articles 16.4 and 16.5 (except for paragraph 4 of Article 16.4) within one year of the date of entry into force of this Agreement; and
 - (c) each Party shall implement each of the other obligations of this Chapter within six months of the date of entry into force of this Agreement.
2. Except as otherwise provided in this Chapter, the date of entry into force in paragraph 6(b) of Article 16.1 means the date of the expiry of the six-month period commencing on the date this Agreement enters into force.